

6-19-90

IRB BRANCH REVIEW - TSS

Record Number(s)

264191

IN 5/15/90 OUT 6/19/90

EFFICACY

FILE OR REG. NO. CORR. 16-817

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 5/11/90

DATE OF SUBMISSION 5/8/90

DATE SUBMISSION ACCEPTED 5/15/90

TYPE PRODUCTS(S): I, D, H, F, N, ~~R~~x S _____

DATA ACCESSION NO(S). none

PRODUCT MGR. NO. 16

PRODUCT NAME(S) MOLE MED

COMPANY NAME Eldon Pickett

SUBMISSION PURPOSE registration application (sort of)

INERT INGREDIENT INFORMATION IS NOT INCLUDED

CHEMICAL & FORMULATION "Oil of rincus" liquid
concentrate

Efficacy Review: MOLE MED, CORR. 16-817
Eldon Pickett
Aurora, IN 47001

200.0 INTRODUCTION

200.1 Uses

INERT INGREDIENT INFORMATION IS NOT INCLUDED

A mixture of "Oil of rincus communis, [REDACTED]
claimed to repel unspecified types of moles from areas sprayed or
sprinkled with the product.

200.2 Background Information

This submission was not considered by RSB to be a registration
application, although the package includes labeling, a Confidential
Statement of Formula (CSF), pesticide registration application form (EPA
Form 8570-1).

Five adhesive-backed printed examples of what appears to be the front
panel of the label were submitted. These examples were connected by
backing, much as are address labels. The existence of such labeling in
apparent market-ready form suggests that the manufacturer either has had
this product on the market or that he was about ready to hit the market
when it occurred to him to apply for registration. Although the examples
of the label s apparent back panel that were submitted where photostatic
copies, it is possible that the items copied also were ready to mount
on product containers.

201.0 DATA SUMMARY

No efficacy data were submitted. I would not accept this product for
registration without some evidence which suggested that the claims are
not totally fanciful.

The list of ingredients quoted above under "Uses" was taken from the
apparent front panel of the labeling. The CSF lists the ingredients as
"AA USP Castor Oil Crystal 0 21 CFR, "[REDACTED]

The "21 CFR" citation for castor oil appears to be an allusion to this
materials exemption from tolerance requirements. This exemption which
currently is published in 40 CFR, Section 180.1001(c), states that the
substance is used as a surfactant. 40 CFR, Section 180.1001 also exempts
[REDACTED]

Apparently in lieu of a Material Safety Data Sheet for [REDACTED] Pickett
has provided a portion of the container label for the product. The text
on the piece of the [REDACTED] attests to the product s mildness:

[REDACTED]

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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[REDACTED]

[REDACTED]

These testimonials do not address satisfactorily the issue of the effects of spraying or sprinkling [REDACTED] plus other materials in the outdoor environment.

The labeling is replete with "instant misbranding" statements such as "ENVIRONMENTALLY SAFE," "contains no harmful chemicals," and "NOT HARMFUL TO ANIMALS, BIRDS OR PLANTS." I believe that the applicant should be provided a copy of the relevant portion of 40 CFR, Section 156.10.

The label claims that the product does not kill moles but that one can use it to "rid" one's yard of moles because moles "will not live or tunnel" in treated areas. Because the label also claims that the product's "scent is not offensive to humans or animals," it is not clear through what modality the product effects moles.

The product is to be diluted with water at a rate of 1 oz. concentrate to 1 gallon of water. The label claims that the product gives coverage of "7500 to 40,000 Sq. Ft. Depending on wet or dry condition of the soil." I assume that this coverage estimate is based upon use of the entire contents of the 32-oz. container. I doubt that Pickett is claiming that a one-gallon preparation will repel moles from a 40,000 square-foot area, even under exceptionally favorable conditions.

202.0 CONCLUSIONS

1. This product is considered to be a "pesticide."
2. Submit complete reports of valid research which demonstrates effectiveness of this formulation. Do not submit testimonials from "satisfied customers" in place of valid efficacy data.
3. The proposed label for this product is inadequate in form and content. Consult 40 CFR, Part 156 for guidance in revising the product label.

Note especially that Section 156.10(a)(5) prohibits the making of false or misleading claims about pesticides, including claims of safety. Statements such as "ENVIRONMENTALLY SAFE," "contains no harmful chemicals," "NOT HARMFUL TO ANIMALS, BIRDS OR PLANTS" are not acceptable on product labels.

The label must include a section captioned "DIRECTIONS FOR USE." This caption must be followed by the statement

"It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

The remainder of the "DIRECTIONS FOR USE" section should be organized under the subheadings "Use Restrictions," "Mixing Directions," and "Application Directions "

The "Use Restrictions" section should indicate the species for which control is claimed, the sites where the product may be used and any other pertinent limitations or general instructions regarding safe and effective use of the product.

The "Application Directions" portion of the label should indicate how the product is to be applied, the rates of application (pounds or gallons of product or mix per unit area) that are appropriate for various sites, and if and under what circumstances retreatment would be appropriate.

[NOTE TO PM: This applicant also needs considerable help with Product Chemistry and other aspects of product labeling.]

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
June 19, 1990